IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CHERYL MOULTRIE and PETER MOULTRIE, Plaintiffs, vs. COLOPLAST CORPORATION; COLOPLAST MANUFACTURING US, LLC, Defendants.	)	2:18-CV-00231-PLD

MEMORANDUM OPINION

Defendants Coloplast Corporation and Coloplast Manufacturing US, LLC (collectively "Coloplast") have moved to exclude the opinions and testimony of Dr. Grant Campbell, an expert witness retained by Plaintiffs Cheryl Moultrie and Peter Moultrie. (ECF No. 61.) For the reasons set forth below, Coloplast's motion will be granted in part and denied in part.

I. Relevant Procedural and Factual History

Plaintiffs, who commenced this action in February 2018, have asserted negligence and strict liability claims that arise out of a synthetic mesh system designed and manufactured by Coloplast. Plaintiffs allege in their Complaint that as a direct result of the 2010 implant of an Aris mid-urethral sling manufactured by Coloplast, Mrs. Moultrie subsequently sustained various complications and injuries, including dyspareunia and urinary tract infections (UTIs). The parties have since stipulated to the dismissal with prejudice of certain causes of action, leaving claims of strict liability for design defect and failure to warn, negligent design, negligent failure to warn and

loss of consortium. Discovery has closed and in a separate opinion and order, Coloplast's motion for summary judgment has been denied.

The instant controversy relates to certain expert causation opinions proffered by Plaintiffs in support of their claims. Specifically, Plaintiffs have submitted expert disclosures and other materials authored by Grant Campbell, M.D., a physician who specializes in obstetrics and gynecology.

By way of background, in September 2018, Dr. Campbell submitted a report in which he expresses the opinion that Mrs. Moultrie's "pelvic pain, urinary tract infections, and dyspareunia" were caused by the erosion of the Aris sling. Dr. Campbell subsequently issued an addendum dated December 16, 2018 in which he indicates that he reviewed three additional sets of medical records, including those of Dr. Jeffrey David, Dr. Claude Tolbert and the Coastal Carolina Medical Center. After his review of these records, he had no revisions or changes to the clinical impressions provided in his September 2018 report.

Dr. Campbell examined Plaintiff Cheryl Moultrie on February 5, 2019 and prepared a "visit note" that summarizes his examination. He then issued another report on March 1, 2019. He opined that her "worsening stress urinary incontinence, pelvic pain, painful intercourse [dyspareunia], and frequent urinary tract infections were caused by the defective Aris bladder neck suspension mesh."

Plaintiffs provided Coloplast with Dr. Campbell's expert disclosures on or about March 1, 2019. These disclosures included his March 1, 2019 report, a summary of his independent medical examination of Mrs. Moultrie, the December 2018 addendum to his September 2018 report, his CV and a "reliance list."

On May 18, 2019, Dr. Campbell issued a "second addendum" to his original clinical summary of September 8, 2018. His report provides additional commentary based on his receipt of additional medical records and his review of the depositions of both Plaintiffs. In this addendum, he states the following:

> Based upon the documented diagnosis of overactive bladder and documented treatment for overactive bladder pre-dating her TOT [Tran-obturator Tape procedure] along with a documented uterine fibroid before the same procedure, **I cannot say with a reasonable degree of medical certainty that Mrs. Moultrie's pelvic pain can be attributed to complications from her TOT. Also, any continued issues of urinary urgency would be difficult to attribute to her TOT complications for the same reason.**

(emphasis added.) Dr. Campbell continued to opine with a reasonable degree of medical certainty that Mrs. Moultrie's continued dyspareunia, urinary tract infections and the return of her stress urinary incontinence can be related to her TOT complications.

Coloplast took the deposition of Dr. Campbell on May 24, 2019. Relevant portions of his testimony will be reviewed as part of the analysis of Coloplast's motion.

II. Standard of Review

Federal Rule of Evidence 702, which governs the admissibility of expert testimony, provides that expert opinions are admissible if: (1) the expert's specialized knowledge will help the trier of fact to understand the evidence or determine a fact at issue; (2) the testimony is based on sufficient facts or data; (3) the testimony is the product of reliable principles and methods; and (4) the expert has reliably applied the principles and methods to the facts of the case. District court judges act as gatekeepers to ensure that the expert testimony is reliable, relevant and helpful to the jury. *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579 (1993). Expert testimony must be

from a qualified source, reliable and fit the facts of the case. *Id.* at 589-91; *Pineda v. Ford Motor Co.,* 520 F.3d 237, 244 (3d Cir. 2008).

As gatekeeper, the court is not the finder of fact but instead must review the methodology applied by an expert witness in order to determine if "good grounds" exist for the opinions expressed. *United States v. Mitchell,* 365 F.3d 215, 244 (3d Cir. 2004). The court should not conflate "its gatekeeping function with the fact-finders' function as the assessor of credibility." *In re TMI Litigation,* 193 F.3d 613, 713 (3d. Cir. 1999). "The evidentiary requirement of reliability is lower than the merits standard of correctness." *In re Paoli R.R. Yard PCB Litigation,* 35 F.3d 717, 744 (3d Cir. 1994). As long as "good grounds" exist for the opinions expressed, they should be tested by the adversary process. *United States v. Mitchell,* 365 F.3d at 244.

As noted in *Magistrini v. One Hour Martinizing Dry Cleaning,* 180 F.Supp.2d 584, 595-96 (D.N.J. 2002), aff'd, 68 F. App'x 356 (3d Cir. 2003):

> As a general matter, the Rules of Evidence "embody a strong and undeniable preference for admitting any evidence" that could potentially assist the trier of fact and Rule 702 is liberally interpreted by the district courts. *Holbrook v. Lykes Bros. Steamship Co., Inc.,* 80 F.3d 777, 780 (3d Cir.1996) (citations omitted). Acknowledging the "liberal thrust" of the Federal Rules of Evidence, the Supreme Court in *Daubert* instructed that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert,* 509 U.S. at 596, 113 S.Ct. 2786. The 2000 Amendments to Rule 702 have not changed this basic premise.

The party offering the expert testimony has the burden of showing that the testimony satisfies the requirements of Rule 702. *Id.; see also Oddi v. Ford Motor Co.,* 234 F.3d 136, 145-46 (3d Cir. 2000).

III. Discussion

In this case, Dr. Campbell was retained by Plaintiffs to offer a causation opinion. He issued multiple reports and addenda that include the information that he considered in reaching his opinions. This included medical records, the findings of other physicians and his physical examination of Mrs. Moultrie. In doing so, he conducted a differential diagnosis. A differential diagnosis is "a technique that involves assessing causation with respect to a particular individual." *Kannankeril v. Terminex International, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997). "Differential diagnosis, or differential etiology, is a standard scientific technique which identifies the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F.Supp.2d 584, 609 (2002); *Heller v. Shaw Industries*, 167 F.3d 146, 154-55 (3d Cir. 1999) (quoting *Paoli*, 35 F.3d at 742 n.8).

An expert's use of a differential diagnosis must be evaluated in order to ensure that the methods employed are reliable. *See Heller*, 167 F.3d at 155. If the diagnosis is challenged by another plausible cause, then it becomes necessary for an expert to offer a good explanation as to why his conclusion remains reliable. *Paoli*, 35 F.3d at 762.

Coloplast raises three bases in its motion for the exclusion of Dr. Campbell's testimony: (1) his opinions are unreliable because he failed to review and rule out Mrs. Moultrie's relevant medical history; (2) certain opinions Dr. Campbell has admitted he cannot offer must be excluded; and (3) his report fails to meet the requirements of Rule 26. Each of these arguments will be addressed in turn.

A. Reliability of Dr. Campbell's Opinions

In its motion, Coloplast asserts that Dr. Campbell's opinions that Mrs. Moultrie's dyspareunia and urinary tract infections were caused by the Aris implant are inherently unreliable and must be excluded because he failed to review and rule out relevant medical history.[1]

Coloplast first notes that Dr. Campbell did not review any medical records from Mrs. Moultrie's pre-implant history before preparing his September 2018 report and December 2018 first addendum. Therefore, he did not know that she had a pre-implant history of dyspareunia. Additionally, Dr Campbell did not "educate himself" about her post-implant motor vehicle accident or exclude vaginal atrophy as an alternative cause. Thus, according to Coloplast, his opinions are fatally deficient.

In his September 8, 2018 report, Dr. Campbell states that he has "reviewed Mrs. Moultrie's medical records and considered her pre-surgical medical and surgical history." Plaintiffs point out that his later addendum and reports reference additional records that he reviewed, and he testified at his deposition that he reviewed all medical records provided to him by Plaintiffs' counsel, which included records that pre-dated Mrs. Moultrie's 2010 implant surgery. Therefore, Dr. Campbell did review her medical history before he authored several of his reports. Whether his review was adequate for purposes of the opinions he expressed is a different issue.

Indeed, the central question is whether Dr. Campbell had "good grounds" for his conclusions. Coloplast asserts that Dr. Campbell did not consider alternative causes for Mrs. Moultrie's injuries, and as such, his opinions must be excluded. As noted in *Heller v. Shaw*

[1] Coloplast's motion to exclude Dr. Campbell's opinions regarding her pelvic pain and urinary incontinence is discussed in Section B of this opinion.

Industries, 167 F.3d 146, 156 (3d Cir. 1999), however, "a medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." Rather, only "where a defendant points to a plausible alternative cause and the doctor offers *no* explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable." *Paoli,* 35 F.3d at 759 n.27. Therefore, it is necessary to review the alternative causes raised by Coloplast.

Coloplast first takes issue with Dr. Campbell's failure to consider Mrs. Moultrie's complaints of dyspareunia before the implant. Dr. Campbell admitted during his deposition that this was "potentially important information" and that he did not consider it in rendering his opinion that her post-implant dyspareunia was caused by the Aris device. (ECF No. 66-10, p.18.) At the same time, however, he testified that during his medical examination of Mrs. Moultrie, he was able to reproduce her dyspareunia upon palpitation, and this finding was important to his opinion on its cause. He opines to a reasonable degree of medical certainty that he could not find any explanation that would explain the location of her pain other than complications from Coloplast's device. Therefore, Dr. Campbell offered an explanation as to why he concluded that the device caused her pain despite her pre-implant history. Simply put, Coloplast's argument goes to weight of his opinion, not to its admissibility.

Coloplast also raises the fact that Dr. Campbell did not "investigate" Mrs. Moultrie's post-implant motor vehicle accident as an alternative cause of her complaints. Dr. Campbell's initial report in September 2018 notes that he reviewed the 2017 records of Plaintiff's treating urologist, Dr. Gwynn, who treated her for urinary incontinence "since car accident in 2015." Dr. Campbell's reports reflect that he was aware of the car accident, as well as Mrs. Moultrie's statement that her

incontinence worsened after the accident. He notes that "[i]t was not felt by Dr. Gwynn that the car accident had any contribution to the eroded sling." His report goes on to state that "I do agree with the consulting Urologist that the main etiology of her incontinence issues was the eroded mesh and cannot think of any reasonable explanation where the car accident would have caused this erosion." He repeats these conclusions in his March 1, 2019 report and May 18, 2019 second addendum. During his deposition, Dr. Campbell was asked about this issue. He confirmed that he relied upon Dr. Gwynn's findings that "the eroded sling was not caused by the accident." He also testified that for trauma to cause erosion, there must be an event that impairs vascular integrity, and he is not aware of any event that would cause devascularization in that area as a result of a motor vehicle accident.

"Depending on the medical condition at issue and on the clinical information already available, a physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available. In fact, it is perfectly acceptable, in arriving at a diagnosis, for a physician to rely on examinations and tests performed by other medical practitioners." *Kannankeril,* 128 F.3d at 807.

In this case, Dr. Campbell was aware of the motor vehicle accident and relied upon Dr. Gwynn's 2017 assessment that it did not cause Mrs. Moultrie's complications, as well as his own training and experience. His reliance is acceptable for purposes of a diagnosis and does not compel a conclusion that his opinion must be excluded. Rather, it goes to the weight, not the admissibility, of his testimony.[2]

---

[2] Coloplast notes that in his deposition, Dr. Gwynn stated that he could not rule out a deceleration injury as a potential cause of mesh erosion, but as Plaintiffs point out, Dr. Gwynn also testified that he has never seen such a result and finds it "a little bizarre" that it could occur. This does not conclusively demonstrate that Dr. Campbell's reliance was misplaced.

Finally, Coloplast asserts that Dr. Campbell failed to rule out vaginal atrophy as an alternative cause of her dyspareunia and urinary tract infections.[3] It argues that the first time that Mrs. Moultrie complained of dyspareunia after the Aris was implanted was in 2017, and it was at the same visit that she first complained of vaginal dryness. While Coloplast emphasizes that the "timing is striking," and Dr. Campbell acknowledged that vaginal atrophy can cause dyspareunia and vaginal dryness, the fact remains that based upon his examination of Mrs. Moultrie, he concluded that her dyspareunia was caused by the Aris implant. He explains the basis for his findings in his reports and in his deposition; moreover, he reviewed her medical records from 2017, referenced them in his September 2018 report and concluded that her symptoms were the result of the implant. He came to the same conclusion following his examination; in fact, as reflected in his February 5, 2019 visit note, Mrs. Moultrie told him that vaginal dryness is not a chronic issue and only occurs upon anticipation of pain with intercourse.[4] Similarly, with respect to the urinary tract infections, Dr. Campbell's second addendum identifies UTIs in 2014 and notes that there was no pre-implant documentation of such infections. Therefore, he concluded that the UTIs are a result of the implant.

Dr. Campbell is not required to consider and eliminate every possible cause in order to express opinions that are admissible at trial. *See Heller,* 167 F.3d at 156. The issues raised by Coloplast go to the weight of his testimony, not to their admissibility. It is the role of the jury to determine if Dr. Campbell's opinions are, in fact, credible. Therefore, Coloplast's motion is denied with respect to his opinions regarding dyspareunia and urinary tract infections.

---

[3] The records cited by Coloplast to support its position that Mrs. Moultrie had developed vaginal atrophy state that she was experiencing vaginal dryness, not vaginal atrophy. (ECF No. 62, p. 13.)
[4] Similarly, her vaginal dryness was referenced as a "psychiatric" issue in the July 2017 records.

B. Exclusion of Opinions Disclaimed by Dr. Campbell

In his May 18, 2019 second addendum and at his deposition, Dr. Campbell acknowledged that he could no longer say with a reasonable degree of medical certainty that Mrs. Moultrie's pelvic pain or continued issues with urinary urgency are the result of her implant. Therefore, Coloplast argues, these opinions must be excluded from his testimony at trial.

In their opposition, Plaintiffs merely state that the court need not determine at this stage if Dr. Campbell's opinions are irrefutable or correct. While they claim that this goes to the weight, not the admissibility, of these opinions, Dr. Campbell has acknowledged that he no longer holds these opinions to the requisite degree of certainty. Indeed, he testified during his deposition that his May 2019 report sets forth every opinion that he will offer, and that he is no longer offering opinions regarding the cause of Mrs. Moultrie's pelvic pain or continued issues with urinary urgency. Therefore, these opinions will be excluded at trial.[5]

In addition, given Dr. Campbell's admission in his deposition that he is not offering any opinion on whether or not Mrs. Moultrie may experience any injury or complaint in the future related to the Aris implant other than continued dyspareunia (ECF No. 66-10, p. 30), Coloplast's motion to exclude any such opinion will be granted as well.

[5] Coloplast also seeks to exclude testimony from Dr. Campbell regarding design or manufacturing defects, the adequacy of warnings or the consent process. Dr. Campbell has not been offered as an expert on these matters and has never expressed any opinions regarding these issues. Obviously, he cannot testify regarding opinions that he has not offered.

C. Coloplast's Rule 26 Argument

Finally, Coloplast argues that Dr. Campbell's opinions should be excluded because his report fails to meet the requirements of Rule 26 of the Federal Rules of Civil Procedure. It notes that his expert disclosure does not provide a list of his prior testimony or rate of compensation. Plaintiffs counter that any such errors are harmless and have been cured. They point out that Dr. Campbell was asked about his fees and his prior testimony during his deposition and provided this information. Thus, according to Plaintiffs, this information was not withheld in bad faith and represents harmless error.

Coloplast has made no showing that Plaintiffs withheld this information in bad faith or that it has sustained any prejudice as a result of the belated production of this information. They had the opportunity to obtain this information during his deposition and this case is not proceeding to trial in the near term. As such, Coloplast has failed to establish that Dr. Campbell's expert opinions should be excluded on this basis.

IV. Conclusion

For the reasons set forth in this opinion, Coloplast's motion is granted in part and denied in part. An appropriate order will follow.

March 16, 2020

BY THE COURT:

PATRICIA L. DODGE
United States Magistrate Judge